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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,924	07/15/2003	Gopi Venkatesh	451194-095	7145
27805	7590	07/11/2006	EXAMINER	
THOMPSON HINE L.L.P.			TRAN, SUSAN T	
P.O. BOX 8801			ART UNIT	
DAYTON, OH 45401-8801			PAPER NUMBER	

1615

DATE MAILED: 07/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/619,924

Applicant(s)

VENKATESH ET AL.

Examiner

Susan T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)          |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. <u>07/06/06</u> .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>01/16/04</u> .  | 6) <input type="checkbox"/> Other: ____.                                    |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7-27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gantt et al. WO 01/43725 A1, in view of Sheth et al. US 4,954,349 or Remington.

Gantt teaches a process for preparing a controlled release potassium chloride (KCl) tablet comprising coating KCl particles with two coating layers by coacervation using polyethylene as a phase separator, blending the coated KCl particles with excipients, and then compressing the blended mixture into tablet (abstract; pages 3-4). First coating layer comprises ethyl cellulose having viscosity of about 90 to about 110 cp (page 3, 1<sup>st</sup> and 2<sup>nd</sup> paragraphs). Second coating layer comprises polyvinyl pyrrolidone, ethyl cellulose, hydroxypropylmethyl cellulose, or combination thereof (page 3, 3<sup>rd</sup> paragraph). Plasticizer such as triacetin, triethyl citrate, dibutyl sebacate, or PEG 400 is included in the second coating composition (page 3, 4<sup>th</sup> paragraph). Excipient includes binder, disintegrant (microcrystalline cellulose), wetting agent (surfactant), and lubricating agent (page 4, last paragraph through page 5, 1<sup>st</sup> paragraph).

Gantt does not explicitly teach the claimed silicon dioxide.

Sheth teaches a KCl compressed tablet comprising the use of lubricant including magnesium stearate and colloidal silicon dioxide (column 5, lines 54-56).

The Remington teaches ingredients for compressed tablet comprising binder, lubricant, disintegrant, and glidant including colloidal silicon dioxide (page 1619).

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the composition of Gantt to use silicon dioxide as a glidant/lubricant/excipient in view of the teaching of Sheth or the Remington, because Sheth teaches the equivalency of magnesium stearate and silicon dioxide, because the Remington teaches the use of silicon dioxide in compressed tablet, and because Gantt teaches the use of pharmaceutically acceptable excipient suitable for compressed tablet.

Gantt further does not expressly teach the claimed tablet hardness. However, the burden is shifted to applicant to show that the compressed tablet of Gantt does not exhibit the claimed properties, because Gantt uses the same ingredients in the same method using the same parameter for the same active, namely potassium chloride; and because Gantt teaches the compressed tablet having similar release profile, *e.g.*, not more than 40% in one hour and not less than 80% over 8 hours (page 5, 3<sup>rd</sup> paragraph).

Claims 6 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gantt et al. WO 01/43725 A1, in view of Sheth et al. US 4,954,349 or Remington, and Oshlack et al. US 5,472,712.

Gantt is relied upon for the reason stated above. Gantt does not teach the claimed plasticizing agent.

Oshlack teaches plasticizer includes diethyl phthalate, triethyl citrate, and triacetin (column 8, lines 34-40). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use diethyl phthalate as a plasticizing agent because Oshlack teaches the equivalency of diethyl phthalate with other well known plasticizing agent, and because Gantt teaches the use of other plasticizing agents in the compressed tablet formulation.

#### ***Pertinent Arts***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Friend et al. is cited as of interest for the teaching of microcapsule using coacervation method.

#### ***Correspondence***

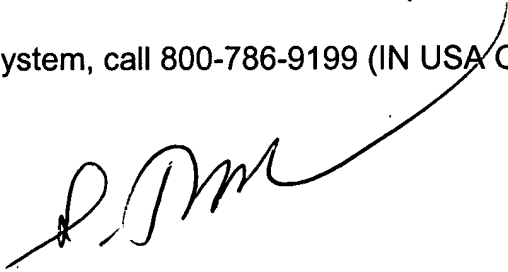
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on Monday through Thursday 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'S. Tran', with a long, sweeping horizontal line extending to the right.

S. Tran  
Examiner  
Art Unit 1615